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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/908,975	07/20/2001	Avi Shoshan	36688-0005	6858

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EXAMINER

GUNTER, DAVID R

ART UNIT PAPER NUMBER

1634

DATE MAILED: 11/15/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/908,975

Applicant(s)

SHOSHAN ET AL.

Examiner

David R. Gunter

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15 and 29-43, drawn to an oligonucleotide library and an array, classified in class 435, subclass 288.3.
- II. Claims 16-28 and 44-58, drawn to a method of measuring gene expression, classified in class 436, subclass 94.
- III. Claim 59-60, drawn to a double stranded RNA, classified in class 536, subclass 22.1.

1. Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the oligonucleotide library or array of group I can be used for a plurality of processes materially different from the method of group II including the identification of DNA binding proteins, and restriction is deemed proper.

2. Groups I and III are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the groups are independent and distinct for two reasons. First, claims 59 and 60 recite that the double stranded RNA of group III is "based on an oligonucleotide selected

Art Unit: 1634

from" the library of group I. The claim does not recite that the RNA of group III is a component of the library, nor does it recite a clear relationship between the sequence of the RNA and the sequences of the nucleic acids of the library. In the absence of a clear recitation of a relationship between the RNA and the library, the inventions are considered to be independent and distinct.

Second, assuming that the RNA molecule of group III is a member of the library of group I or a fragment of a member of the library, the RNA molecule has substantially different modes of operation, functions, and effects than the library or microarray of group I. The mode of operation of the RNA molecule comprises administration of the molecule to an intact cell or organism with the intended function and effect of "interfer[ing] with translation of mRNA" to prevent expression of a protein. The mode of operation of the library or array comprises combining the library or array with a set of messenger RNAs with the intended function and effect of specifically hybridizing to these messenger RNAs in order to detect their presence. Because the inventions of groups I and III differ in their mode of operation, effects, and functions, restriction is deemed proper.

3. Groups II and III are independent and distinct. Inventions are independent and distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, there is no recited relationship between the method of group II and the RNA molecule of group III. The method of group II does not make, use, or otherwise recite a relationship to the RNA molecule of group III, and therefore restriction is deemed proper.

Art Unit: 1634

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species

Claims 1-58 are generic to a plurality of disclosed patentably distinct species. The claims recite libraries, arrays, and methods of using libraries and arrays derived from tissues with numerous animals of origin (human, claim 2; rat, claim 3; mouse, claim 4), numerous pathologic conditions (pathological, claim 6; neoplastic, claim 7;) and numerous stages of development (claim 8). Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

The applicant is required to elect

Art Unit: 1634

- a. a single organism from which the library / array is derived or toward which the method is directed.
- b. a single pathologic state of the tissue from which the library / array is derived or toward which the method is directed. The examiner notes that the applicant may elect normal tissue free from a pathologic condition instead of a specific pathologic state.
- c. a single stage of development for the tissue from which the library / array is derived or toward which the method is directed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David R. Gunter whose telephone number is (703) 308-1701.

The examiner can normally be reached on 9:00 - 5:00 M - F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-9212 for regular communications and (703) 308-8724 for After Final communications.

Application/Control Number: 09/908,975


Page 6

Art Unit: 1634

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.



David R. Gunter, DVM, PhD
November 7, 2002



B. J. FORMAN
PATENT EXAMINER